

registration, transplant recipient registration and follow-up, and living donor registration and follow-up.

(b) *Standard: Clinical experience.* To be considered for initial approval, an organ-specific transplant center must generally perform 10 transplants over a 12-month period.

(c) *Standard: Outcome requirements.* CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants, if applicable. Except for lung transplants, CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using the data contained in the most recent Scientific Registry of Transplant Recipients (SRTR) center-specific report.

(2) The required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report.

(3) CMS will not consider a center's patient and graft survival rates to be acceptable if:

(i) A center's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate or expected graft survival rate; and

(ii) All three of the following thresholds are crossed over:

(A) The one-sided p-value is less than 0.05,

(B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and

(C) The number of observed events divided by the number of expected events is greater than 1.5.

(d) *Exceptions.* (1) A heart-lung transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for heart-lung transplants performed at the center.

(2) An intestine transplant center is not required to comply with the outcome performance requirements in paragraph (c) of this section for intestine, combined liver-intestine or multi-visceral transplants performed at the center.

(3) A pancreas transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for pancreas transplants performed at the center.

(4) A center that is requesting initial Medicare approval to perform pediatric transplants is not required to comply with the clinical experience requirements in paragraph (b) of this section prior to its request for approval as a pediatric transplant center.

(5) A kidney transplant center that is not Medicare-approved on the effective date of this rule is required to perform at least 3 transplants over a 12-month period prior to its request for initial approval.

§ 482.82 Condition of participation: Data submission, clinical experience, and outcome requirements for re-approval of transplant centers.

Except as specified in paragraph (d) of this section, and § 488.61 of this chapter, transplant centers must meet all data submission, clinical experience, and outcome requirements in order to be re-approved.

(a) *Standard: Data submission.* No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of the required data submissions on all transplants (deceased and living donor) it has performed over the 3-year approval period. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow-up, and living donor registration and follow-up.

(b) *Standard: Clinical experience.* To be considered for re-approval, an organ-specific transplant center must generally perform an average of 10 transplants per year during the re-approval period.

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(c) *Standard: Outcome requirements.* CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants if applicable. Except for lung transplants, CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using data contained in the most recent SRTR center-specific report.

(2) The required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report.

(3) CMS will not consider a center's patient and graft survival rates to be acceptable if:

(i) A center's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate and graft survival rate; and

(ii) All three of the following thresholds are crossed over:

(A) The one-sided p-value is less than 0.05,

(B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and

(C) The number of observed events divided by the number of expected events is greater than 1.5.

(d) *Exceptions.* (1) A heart-lung transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for heart-lung transplants performed at the center.

(2) An intestine transplant center is not required to comply with the outcome requirements in paragraph (c) of this section for intestine, combined liver-intestine, and multivisceral transplants performed at the center.

(3) A pancreas transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome

requirements in paragraph (c) of this section for pancreas transplants performed at the center.

(4) A center that is approved to perform pediatric transplants is not required to comply with the clinical experience requirements in paragraph (b) of this section to be re-approved.

TRANSPLANT CENTER PROCESS REQUIREMENTS

§ 482.90 Condition of participation: Patient and living donor selection.

The transplant center must use written patient selection criteria in determining a patient's suitability for placement on the waiting list or a patient's suitability for transplantation. If a center performs living donor transplants, the center also must use written donor selection criteria in determining the suitability of candidates for donation.

(a) *Standard: Patient selection.* Patient selection criteria must ensure fair and non-discriminatory distribution of organs.

(1) Prior to placement on the center's waiting list, a prospective transplant candidate must receive a psychosocial evaluation, if possible.

(2) Before a transplant candidate on its waiting list, the candidate's medical record must contain documentation that the candidate's blood type has been determined.

(3) When a patient is placed on a center's waiting list or is selected to receive a transplant, the center must document in the patient's medical record the patient selection criteria used.

(4) A transplant center must provide a copy of its patient selection criteria to a transplant patient, or a dialysis facility, as requested by a patient or a dialysis facility.

(b) *Standard: Living donor selection.* The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant centers must:

(1) Ensure that a prospective living donor receives a medical and psychosocial evaluation prior to donation,